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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/525,648

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John P Wikswo

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EXAMINER

DOE, SHANTA G

ART UNIT

PAPER NUMBER

1797

NOTIFICATION DATE

DELIVERY MODE

12/10/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/525,648	Applicant(s) WIKSWO ET AL.	
	Examiner SHANTA G. DOE	Art Unit 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 February 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-155 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 144-155 is/are allowed.
- 6) ☒ Claim(s) 1,30,31 and 42-143 is/are rejected.
- 7) ☒ Claim(s) 2-29, and 32-40 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 February 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>See Continuation Sheet</u> . | 6) <input type="checkbox"/> Other: _____ |

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :8/3/2007, 4/2/2007, 9/26/2006, 7/17/2006 &4/21/2006.

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
2. Claims 42-143 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
3. Claims 42-143 recite the limitation "the chamber". There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
2. Claims 1, 30, and 31 are rejected under 35 U.S.C. 102(e) as being anticipated by Cosby et al (US 2003/0107946).

Regarding claim 1, Cosby discloses a bioreactor (110) comprising:

- a. a first substrate (114) having a first surface, an opposite second surface and edges (see fig 7);
- b. a second substrate (112) having a first surface and an opposite second surface, defining a cavity(136) with a bottom surface (bottom of the chamber 136), wherein the bottom surface is located there between the first surface and the second surface, and wherein the first surface of the first substrate is received by the second surface of the second substrate to cover the cavity so as to form a chamber for receiving cells and a liquid medium; and
- c. a port (inlets 126, 128 and outlet 132,134) formed between the bottom surface and the first surface of the second substrate with a first opening (126) and an opposite, second opening (132), wherein the port is in fluid communication with the chamber through the first opening to allow a stream of substance to be introduced into the chamber through the port substantially along a first direction (see fig 7, [0006], [0008] and [0035]).

Regarding claim 30, Cosby discloses the bioreactor of claim 1, wherein the second substrate (substrate (112) can be made of glass) is fabricated from glass, Mylar, PDMS, silicon, a polymer, a semiconductor, or any combination of them (see [0035]).

Regarding claim 31, Cosby discloses the bioreactor of claim 1, wherein the first

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substrate (cover slip is made from glass) is at least partially optically transparent (see [0019]).

3. Claims 1, 30 and 31 are rejected under 35 U.S.C. 102(e) as being anticipated by Wilding et al (US 6,660,517).

Regarding claim 1, Wilding discloses a bioreactor (10) comprising:

- a. a first substrate (12) having a first surface, an opposite second surface and edges (see 2A);
- b. a second substrate (14) having a first surface and an opposite second surface, defining a cavity(22B, 22A) with a bottom surface (bottom of the chamber 22A and 22B), wherein the bottom surface is located there between the first surface and the second surface, and wherein the first surface of the first substrate is received by the second surface of the second substrate to cover the cavity so as to form a chamber for receiving cells and a liquid medium; and
- c. a port (inlets 16 A and B) formed between the bottom surface and the first surface of the second substrate with a first opening (16 A) and an opposite, second opening (16B), wherein the port is in fluid communication with the chamber through the first opening to allow a stream of substance to be introduced into the chamber through the port substantially along a first direction (see fig 5,7, col. 4 lines 10-35; col. 5 lines 29-46 ,60-65; col. 10 lines 40-45; col. 12 lines 15-35; col. 14 lines 17-25 and col. 18 lines 15-22).

Regarding claim 30, Wilding discloses the bioreactor of claim 1, wherein the second substrate (substrate 14 can be made of silicon) is fabricated from glass, Mylar, PDMS, silicon, a polymer, a semiconductor, or any combination of them (col. 6 line 33)).

Regarding claim 31, Wilding discloses the bioreactor of claim 1, wherein the first substrate (cover (12) is made from glass) is at least partially optically transparent (col. 4 lines 17 -19col.14 line 17-25 and col. 18 lines 15-22).

Allowable Subject Matter

4. Claims 2-29 and 39-41 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Regarding claim 2 and its dependent (direct or indirect dependent) claims the prior art along or in combination fails to disclose the bioreactor of claim 1 wherein the second substrate further defines a third opening opposite a fourth opening adapted for allowing a flow of liquid to be introduced into the chamber through the third opening and away from the chamber through the fourth opening along a second direction wherein the second direction is substantially perpendicular to the first direction.

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5. Claims 42 -143 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Regarding claim 42 and its dependent claims, the prior art fails to disclose bioreactor having first substrate, a second substrate having a first surface and an opposite second surface defining a cavity with a bottom surface and a perfusion means in fluid communication with the chamber/cavity to allow diffusional exchange of nutrient and metabolic byproduct with the chamber.

Regarding claim 89 and its dependent claims the prior art fails to disclose bioreactor having first substrate, a second substrate having a first surface and an opposite second surface defining a cavity with a bottom surface and a filter dividing the chamber/cavity into first and second sub-chambers wherein the filter has a porosity to allow the first and second sub-chamber to be in fluid communications.

Regarding claim 109 and it dependent claim, the prior art fails to disclose bioreactor having first substrate, a second substrate having a first surface and an opposite second surface defining a cavity with a bottom surface; a perfusion means in fluid communication with the chamber /cavity to allow diffusional exchange of nutrient and metabolic byproduct with the chamber and a filter dividing the chamber/cavity into first

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and second sub-chambers wherein the filter has a porosity to allow the first and second sub-chamber to be fluid communications.

6. Claims 144 – 155 are allowed.

7. The following is an examiner's statement of reasons for allowance:

Regarding claim 144 and its dependent claims, the prior art fails to disclose a layered perfusion system comprising a filter having a plurality of pores and perfusion supply network in fluid communication with the filter through the pores.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHANTA G. DOE whose telephone number is (571)270-3152. The examiner can normally be reached on Mon-Fri 8am-5pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Walter Griffin can be reached on 571-272-1447. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

GSD

/Walter D. Griffin/
Supervisory Patent Examiner, Art Unit 1797